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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,529	02/17/2006	Charlotte Lindhardt	MERCK3133	5069

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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER

MA, JAMESON Q

ART UNIT	PAPER NUMBER
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1797

NOTIFICATION DATE	DELIVERY MODE
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06/23/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/568,529	Applicant(s) LINDHARDT ET AL.	
	Examiner JAMESON Q. MA	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I in the reply filed on 4/3/2009 is acknowledged. The traversal is on the ground(s) that the Office Action fails to provide rationale as to why search/examination beyond a single claim would constitute an undue burden. This is not found persuasive because the instant application is subject to lack of unity practice, and it has been found that the special technical feature of the restricted claims was not found to be a contribution over the prior art, see Office action dated 10/3/2008.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 and 9-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 recites the limitation "the biological material or particles" in segment 'e'. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 10-14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schrecengost et al. (US 6,660,489) in view of Copeland et al. (6,844,458), further in view of Grubbs et al. (US 4,945,144) or Friswell et al. (US 5,490,872) and Grubbs et al. (US 4,945,144).

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Regarding claims 1, 12-14 and 16. Schrecengost discloses a method for extraction and concentration of a hydrophilic compound (ATP) dispersed in a liquid matrix comprising:

providing a sample of a liquid (see C2/L49-50: biological sample)

adding to said sample an aqueous capture solution (see C3/L6-14) comprising an anionic surfactant (see C4/L22-25: SDS or sulfate ion), wherein said surfactant improves the yield of the hydrophilic compound extracted from the matrix

measuring the hydrophilic compound in the aqueous phase (see abstract).

The mixing of said sample and said capture solution thoroughly and allowing an aqueous phase to separate from the sample phase are inherent properties of a method wherein an extractant is mixed with a biological sample.

Schrecengost does not explicitly disclose the liquid as a hydrophobic matrix. However, the reference does disclose that many industries have a need for rapid microbial monitoring and that one of the most visible industries with this requirement is the food manufacturing industry (see C1/L19-31).

Copeland discloses that microbial contamination is found in crude vegetable oil (see C2/L25-39). Vegetable oil is a hydrophobic matrix.

It would have been obvious to one of ordinary skill in the art at the time of invention to use as the method of Schrecengost with vegetable oil as the food product, as doing so would have resulted in nothing more than choosing from a finite number of

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identified and predictable solutions of food products at-risk of microbial contamination, as disclosed by both Schrecengost and Copeland.

Modified Schrecengost does not explicitly disclose the capture solution containing a water soluble dye. However the reference does disclose that a cationic extractant such as benzalkonium chloride, benzethonium chloride, or dodecyl trimethyl ammonium chloride (see C4/L53-61).

Grubbs teaches the cationic extractant methylene blue (see C10/L49-50).

It would have been obvious to one of ordinary skill in the art at the time of invention to substitute for the disclosed cationic extractants of Schrecengost, with the cationic methylene blue as taught by Grubbs, because doing so would have resulted in nothing more than the simple substitution of known cationic extractants with a reasonable expectation of success.

Alternatively, Friswell teaches that Dyes and markers are needed to clearly distinguish chemically or physically similar liquids (see C1/L26-27). Schrecengost teaches many different permutations of chemically similar extractant solutions (see examples). Further, Grubbs teaches the dye methylene blue.

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate a dye as taught by Friswell into the extractant solutions taught by modified Schrecengost, in order to distinguish the many types of chemically similar liquids. It would have further been obvious to incorporate methylene blue as the dye

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because doing so would have resulted in nothing more than choosing from a finite number of identified and predictable dye solutions.

Regarding claims 10-11, modified Schrecengost discloses all of the claim limitations as set forth above. Additionally, Schrecengost discloses that multiple extractants can be used in the same capture solution (see C7:L30-32: a sulfate ion and Tween 20, which is a non-ionic surfactant, were used in combination).

9. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schrecengost et al. (US 6,660,489) in view of Copeland et al. (6,844,458), further in view of Grubbs et al. (US 4,945,144) or Friswell et al. (US 5,490,872) and Grubbs et al. (US 4,945,144) as applied to claims 1, 10-14, and 16 above, and further in view of Calvo Salve et al. (US 5,843,509).

Regarding claim 9, modified Schrecengost discloses all of the claim limitations as set forth above. Additionally, Schrecengost discloses that an anionic substance (for example, SDS) is used to neutralize the positive charge of the ATP extractant (see C4/L53-61). However, the reference does not explicitly disclose lecithin as an extractant.

SDS is a well-known anionic substance and surfactant (surface active agent).

Calvo Salve discloses that lecithin is a natural surfactant (C1/L24) and that it is anionic (see C2/L26).

It would have been obvious to one of ordinary skill in the art at the time of invention to substitute lecithin as taught by Calvo Salve, for SDS in the extractant mixture of modified Schrecengost, because doing so would have resulted in the simple

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substitution of known anionic surfactants capable of neutralizing a positive charge, with a reasonable expectation of success.

10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schrecengost et al. (US 6,660,489) in view of Copeland et al. (6,844,458), further in view of Grubbs et al. (US 4,945,144) or Friswell et al. (US 5,490,872) and Grubbs et al. (US 4,945,144) as applied to claims 1, 10-14, and 16 above, and further in view of Lawrence et al. (US 2002/0197631).

Regarding claim 15, modified Schrecengost discloses all of the claim limitations as set forth above. The reference is directed to extracting ATP from a sample for measurement. The reference does not disclose the capture solution further comprising a phosphate buffer.

Lawrence discloses that a capture solution containing phosphate buffer promotes the dissolution of cellular material out of cells. Additionally, Lawrence discloses that the capture solution is compatible with detergents such as SDS (see [0107]).

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate a phosphate buffer taught by Lawrence, into the extractant mixture/capture solution of modified Schrecengost, because doing so would promote the dissolution of cellular materials (including ATP) out of cells, which would enhance its detectability in a luciferase assay as disclosed by Schrecengost.

Response to Arguments

11. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMESON Q. MA whose telephone number is (571)270-7063. The examiner can normally be reached on M-R 8:30 AM - 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JM

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

June 17, 2009